Complete Summary

GUIDELINE TITLE

Managing drug interactions in the treatment of HIV-related tuberculosis.

BIBLIOGRAPHIC SOURCE(S)

Centers for Disease Control and Prevention (CDC). Managing drug interactions in the treatment of HIV-related tuberculosis. Atlanta (GA): Centers for Disease Control and Prevention (CDC); 2007 Dec. [55 references]

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version:

Centers for Disease Control and Prevention (CDC). Updated guidelines for the use of rifamycins for the treatment of tuberculosis among HIV-infected patients taking protease inhibitors or nonnucleoside reverse transcriptase inhibitors. Atlanta (GA): Centers for Disease Control and Prevention (CDC); 2004 Jan 20. 6 p. [30 references]

Centers for Disease Control and Prevention. Prevention and treatment of tuberculosis among patients infected with human immunodeficiency virus: Principles of therapy and revised recommendations. MMWR Recomm Rep 1998 Oct 30;47(RR-20):1-58. [162 references] PubMed

Updated guidelines for the use of rifabutin or rifampin for the treatment and prevention of tuberculosis among HIV-infected patients taking protease inhibitors or nonnucleoside reverse transcriptase inhibitor. MMWR Morb Mortal Wkly Rep 2000 Mar 10;49(9):185-9. [10 references] PubMed

** REGULATORY ALERT **

FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse (NGC): This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

 July 24, 2008, Ziagen (abacavir sulfate): The U.S. Food and Drug Administration (FDA) has notified the maker of abacavir and abacavircontaining medications of the need to add information to the current BOXED WARNING about the recommendation to test all patients for the HLA-B*5701

- allele before starting or restarting therapy with abacavir or abacavircontaining medications.
- July 8, 2008, Fluoroquinolones (ciprofloxacin, norfloxacin, ofloxacin, levofloxacin, moxifloxacin, gemifloxacin): A BOXED WARNING and Medication Guide are to be added to the prescribing information to strengthen existing warnings about the increased risk of developing tendinitis and tendon rupture in patients taking fluoroquinolones for systemic use.

COMPLETE SUMMARY CONTENT

** REGULATORY ALERT **

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INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT

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SCOPE

DISEASE/CONDITION(S)

- Tuberculosis (TB)
- Human immunodeficiency virus (HIV) infection

GUIDELINE CATEGORY

Management Treatment

CLINICAL SPECIALTY

Family Practice
Infectious Diseases
Internal Medicine
Obstetrics and Gynecology
Pediatrics

INTENDED USERS

Advanced Practice Nurses Allied Health Personnel Nurses Physician Assistants

GUIDELINE OBJECTIVE(S)

To provide the clinician with updated recommendations for managing the drugdrug interactions that occur when using antiretroviral therapy during tuberculosis treatment

TARGET POPULATION

Human immunodeficiency virus (HIV)-infected adults and children with active or latent tuberculosis

INTERVENTIONS AND PRACTICES CONSIDERED

- 1. Coadministration of anti-tuberculosis and antiretroviral therapies
 - Anti-tuberculosis therapy: rifamycins (rifampin, rifabutin)
 - Antiretroviral therapies
 - Nonnucleoside reverse transcriptase inhibitors(NNRTI) (efavirenz, nevirapine)
 - Protease inhibitors (ritonavir, indinavir, lopinavir, atazanavir, saquinavir)
 - Nucleoside reverse transcriptase inhibitors (NRT) (zidovudine, lamivudine, abacavir, tenofovir)
 - Other (maraviroc, raltegravir)
- 2. Altered dosing to adjust for drug-drug interactions
- 3. Consideration of special populations (pregnant women, children, patients with multidrug-resistant tuberculosis)
- 4. Monitoring for response to therapy, drug-related toxicity, drug interactions

MAJOR OUTCOMES CONSIDERED

- Adverse drug interactions
- Drug tolerability and toxicity
- Drug effectiveness
- Adherence to therapy

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Not stated

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not stated

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Note from the National Guideline Clearinghouse (NGC) and the Centers for Disease Control and Prevention (CDC): Changes from previous versions of these guidelines include: an effort to obtain and summarize the clinical experience of using specific antiretroviral regimens during tuberculosis treatment (not just pharmacokinetic data), a table summarizing the clinical experience with key antiretroviral regimens and providing recommended regimens (Table 1 in the original guideline document), and sections on treatment for special populations (young children, pregnant women, patients with drug-resistant tuberculosis). Drug-drug interaction data are included for antiretroviral drugs that have been approved or are currently available through expanded access programs in the United States; these recommendations will be updated as additional antiretroviral drugs progress become available.

The key interactions, and the focus of this document, are those between the rifamycin antibiotics and four classes of antiretroviral drugs: protease inhibitors, non-nucleoside reverse-transcriptase inhibitors [NNRTI], CCR5-receptor antagonists, and integrase inhibitors. Only two of the currently available antiretroviral drug classes, the nucleoside analogues (other than zidovudine) and enfuvirtide (a parenteral entry inhibitor) do not have significant interactions with the rifamycins.

The Role of Rifamycins in Tuberculosis Treatment

Despite the complexity of these drug interactions, the key role of the rifamycins in the success of tuberculosis treatment mandates that the drug-drug interactions between the rifamycins and antiretroviral drugs be managed, not avoided by using tuberculosis treatment regimens that do not include a rifamycin or by withholding antiretroviral therapy until completion of anti-tuberculosis therapy among patients with advanced immunodeficiency. Therefore, patients with human immunodeficiency virus (HIV)-related tuberculosis should be treated with a regimen including a rifamycin for the full course of tuberculosis treatment, unless the isolate is resistant to the rifamycins or the patient has a severe side effect that is clearly due to the rifamycins.

Furthermore, patients with advanced HIV disease (CD4 cell count <100 cells/mm³) have an increased risk of acquired rifamycin resistance if treated with a rifamycin-containing regimen administered once or twice-weekly. The rifamycin-based regimen should be administered daily (5-7 days per week) for at least the first 2 months of treatment among patients with advanced HIV disease.

Rifampin and Antiretroviral Therapy

The most important drug-drug interactions in the treatment of HIV-related tuberculosis are those between rifampin and the NNRTIs, efavirenz and nevirapine. Rifampin is the only rifamycin available in most of the world, and initial antiretroviral regimens in areas with high rates of tuberculosis consist of efavirenz or nevirapine (in combination with nucleoside analogues). Furthermore, because of its potency and durability in randomized clinical trials, efavirenz-based therapy is a preferred option for initial antiretroviral therapy in developed countries.

Rifampin and Efavirenz

Rifampin causes a measurable, though modest, decrease in efavirenz concentrations (see $\underline{\text{Table 2}}$ in the original guideline document). Increasing the dose of efavirenz from 600 mg daily to 800 mg daily compensates for the effect of rifampin, but it does not appear that this dose increase is necessary to achieve excellent virological outcomes of therapy. Trough concentrations of efavirenz, the best predictor of its virological activity, remain well above the concentration necessary to suppress HIV in vitro among patients on concomitant rifampin. Therefore, this combination—efavirenz-based antiretroviral therapy and rifampin-based tuberculosis treatment, at their standard doses—is the preferred treatment for HIV-related tuberculosis (see $\underline{\underline{Table 1}}$ in the original guideline document). Some experts recommend the 800 mg dose of efavirenz for patients weighing >60 kg.

Alternatives to Efavirenz-Based Antiretroviral Therapy

Alternatives to efavirenz-based antiretroviral therapy are needed for patients with HIV-related tuberculosis: efavirenz cannot be used during pregnancy (at least during the first trimester), some patients are intolerant to efavirenz, and some are infected with NNRTI-resistant strains of HIV.

Rifampin and Nevirapine

Rifampin decreases serum concentrations of nevirapine by 20-55% (see Table 1 in the original guideline document). The common toxicities of nevirapine—skin rash and hepatitis—overlap common toxicities of some first-line anti-tuberculosis drugs. Furthermore, nevirapine-based regimens are not recommended for patients with higher CD4 cell counts (>350 cells/mm³ for men, >250 cells/mm³ for women) because of increased risk of severe hypersensitivity reactions. Therefore, there are concerns about the efficacy and safety of using nevirapinebased antiretroviral therapy during rifampin-based tuberculosis treatment. At present, there have been no studies comparing efavirenz vs. nevirapine-based antiretroviral therapy among patients being treated for tuberculosis. Trough serum concentrations of nevirapine among patients on concomitant rifampin often exceed the concentration necessary to suppress HIV in vitro. Several cohort studies have shown high rates of viral suppression among patients receiving nevirapine-based antiretroviral therapy. The risk of hepatitis among such patients was also comparable to patients receiving first-line tuberculosis treatment without antiretroviral therapy. Despite the interaction with rifampin, nevirapine-based antiretroviral therapy appears to be reasonably effective and well-tolerated among patients being treated for tuberculosis.

These studies are neither adequately powered nor reported in sufficient detail to fully answer the concerns about the efficacy and safety of nevirapine-based antiretroviral therapy during tuberculosis treatment. However, the collected experience is sufficient to make nevirapine an alternative for patients unable to take efavirenz and who do not have access to rifabutin. Some investigators have suggested using an increased dose of nevirapine among patients on rifampin. However, a recent randomized trial comparing standard dose nevirapine (200 mg twice-daily) to a higher dose (300 mg twice daily) among patients on rifampin demonstrated an increased risk of nevirapine hypersensitivity among patients randomized to the higher dose of nevirapine. Therefore, the standard dose of

nevirapine should be used among patients on rifampin (200 mg daily for 2 weeks, followed by 200 mg twice-daily).

Other Antiretroviral Regimens for Use with Rifampin

For patients who are infected with NNRTI-resistant HIV, neither efavirenz nor nevirapine will be effective. Unfortunately, there is little clinical experience with alternatives to NNRTI-based therapy among patients being treated with rifampin. Standard doses of protease inhibitors cannot be given with rifampin (see $\underline{\text{Table 1}}$ in the original guideline document); the >90% decreases in trough concentrations of the protease inhibitors would surely make them ineffective. Most protease inhibitors are given with low-dose ritonavir (100-200 mg per dose of the other protease inhibitor). However, low-dose ritonavir does not overcome the effects of rifampin; serum concentrations of indinavir, lopinavir, and atazanavir were decreased by >90% when given with the standard ritonavir boosting dose (100 mg) in the presence of rifampin, and a once-daily regimen of ritonavir-boosted saquinavir (saquinavir 1600 mg + ritonavir 200 mg) resulted in inadequate concentrations of saquinavir. Therefore, standard protease inhibitor regimens, whether boosted or not, cannot be given with rifampin.

The dramatic effects of rifampin on serum concentrations of other protease-inhibitors can be overcome with high-doses of ritonavir (400 mg twice-daily, "super-boosted protease inhibitors") or by doubling the dose of the co-formulated form of lopinavir/ritonavir. However, high rates of hepatoxicity occurred among healthy volunteers treated with rifampin and ritonavir-boosted saquinavir (saquinavir 1000 mg + ritonavir 100 mg twice-daily) and those treated with rifampin and lopinavir/ritonavir (either as lopinavir 400 mg + 400 mg ritonavir twice-daily or as lopinavir 800 mg + ritonavir 200 mg twice-daily).

Whether patients with HIV-related tuberculosis will have the same high rates of hepatotoxicity when treated with super-boosted protease inhibitors or double-dose lopinavir/ritonavir has not been adequately studied. Among patients receiving rifampin-based tuberculosis treatment, the combination of ritonavir-boosted saquinavir (400 mg of each, twice daily) was not well-tolerated. The initial positive experience with super boosted lopinavir among young children (see below) suggests that these regimens may be tolerable and effective among at least some patients with HIV-related tuberculosis. However, these regimens should only be used with close clinical and laboratory monitoring for possible hepatoxicity, when there is a pressing need to start antiretroviral therapy.

Regimens composed entirely of nucleoside analogues are less active than combinations of two classes of antiretroviral drugs (e.g., NNRTI + nucleosides). A regimen of zidovudine, lamivudine, and the nucleotide agent, tenofovir, has been reported to be active among patients on rifampin-based tuberculosis treatment. However, this regimen has not been compared to standard initial antiretroviral therapy (e.g., efavirenz + 2 nucleosides). Finally, a quadruple regimen of zidovudine, lamivudine, abacavir, and tenofovir has been reported to be as active as an efavirenz-based regimen in an initial small trial. While these regimens of nucleosides and nucleotides cannot be recommended as preferred therapy among patients receiving rifampin, their lack of predicted clinically-significant interactions with rifampin make them an acceptable alternative, for patients unable to take NNRTIs or those with NNRTI-resistant HIV.

Rifampin has substantial interactions with the recently-approved CCR5-receptor antagonist, maraviroc. An increased dose of maraviroc has been recommended to allow concomitant use of rifampin and maraviroc, but there is no reported clinical experience with this combination. Rifampin decreases the trough concentrations of raltegravir, the recently-approved integrase inhibitor, by ~ 60%. Because the antiviral activity of raltegravir 200 mg twice daily was very similar to the activity of the licensed dose (400 mg twice-daily), the current recommendation is to use the standard dose of raltegravir in a patient receiving concomitant rifampin. However, this combination should be used with caution—there is very little clinical experience with using concomitant raltegravir and rifampin. Finally, rifampin is predicted to substantially decrease the concentrations of etravirine (a second-generation NNRTI currently available through an expanded access program). Additional drug-interaction studies will be needed to further evaluate whether these new agents can be used among patients receiving rifampin-based tuberculosis treatment.

Rifabutin and Antiretroviral Drugs

Rifabutin is as effective for tuberculosis treatment as rifampin, but has much less effect on drugs metabolized through the cytochrome P450 3A (CYP3A) system (see <u>Table 3</u> in the original guideline document). However, rifabutin is either not available or is very expensive in countries with high rates of HIV-related tuberculosis. Furthermore, some antiretroviral drugs have a substantial effect on rifabutin concentrations, necessitating somewhat complex dosing guidelines for rifabutin in the setting of antiretroviral therapy (see <u>Table 3</u> in the original guideline document). In addition to their complexity, there is another potential problem of using rifabutin for tuberculosis treatment. If a patient whose rifabutin dose was decreased in response to antiretroviral therapy then stops taking the interacting drug (e.g., ritonavir), the resulting rifabutin concentrations are likely to be sub-therapeutic. These factors, in addition to the limited availability of the drug, limit the use of rifabutin in the treatment of HIV-related tuberculosis.

Rifabutin and Protease Inhibitors

Rifabutin has little, if any effect on the serum concentrations of protease-inhibitors (other than unboosted saquinavir). Though no comparative studies have been done, the combination of rifabutin (if available) with protease-inhibitor based antiretroviral therapy is the preferred form of therapy for patients unable to take NNRTI-based antiretroviral therapy (see <u>Table 1</u> in the original guideline document). As above, there are concerns about the safety of super-boosted protease-inhibitors and the efficacy of nucleoside-only regimens in the setting of rifampin-based tuberculosis treatment. The protease-inhibitors, particularly if pharmacologically boosted with ritonavir, markedly increase serum concentrations and toxicity of rifabutin. Therefore, the dose of rifabutin should be decreased when used with protease-inhibitors (see Table 3 in the original guideline document). As above, the decreased dose of rifabutin would be sub-therapeutic if the patient stopped taking the protease-inhibitor without adjusting the rifabutin dose. Therefore, adherence to the protease-inhibitor should be assessed with each dose of directly observed tuberculosis treatment; one convenient way to do so is to give a supervised dose of protease-inhibitor at the same time as the directly observed dose of tuberculosis treatment.

Special Populations

Pregnant Women

In the absence of pharmacokinetic data and published clinical experience it is difficult to formulate guidelines for the management of drug-drug interactions during the treatment of HIV-related tuberculosis among pregnant women. Nevirapine-based therapy could be used among women on rifampin-based tuberculosis treatment, with the caveat that there be a good monitoring system for symptoms and laboratory tests for hepatotoxicity. Efavirenz-based therapy may be an option during the later stages of pregnancy. The quadruple nucleoside/nucleotide regimen (zidovudine, lamivudine, abacavir, and tenofovir) is an alternative, though additional experience is required, particularly during pregnancy. Finally, despite their sub-optimal activity, triple nucleoside or nucleoside/nucleotide regimens are an alternative during pregnancy. Where rifabutin is available, the preferred option is protease-inhibitor-based antiretroviral therapy.

Children

In addition to the complexities raised by the drug interactions discussed above, children with HIV-related tuberculosis raise other challenges. There are very limited data on the absorption, metabolism, and elimination of anti-tuberculosis drugs among children, particularly among very young children (<2 years of age).

Some antiretroviral agents are not yet available in suspension formulations, and there are limited pharmacokinetic data for all antiretroviral drugs among young children. The use of single-dose nevirapine selects for NNRTI-resistant strains among those infants who are infected despite perinatal prophylaxis, and such children have inferior outcomes if subsequently treated with nevirapine-based combination antiretroviral therapy. Therefore, there is understandable reluctance to use NNRTI-based therapy among perinatally-infected infants who were exposed to single-dose nevirapine. As above, the inability to use NNRTI-based antiretroviral therapy limits options for antiretroviral therapy among children receiving rifampin-based tuberculosis treatment.

There are emerging, though unpublished, pharmacokinetic data and clinical experience with using protease-inhibitor-based antiretroviral therapy among young children (<5 years of age) with HIV-related tuberculosis. Children treated with super-boosted lopinavir (ritonavir in addition to doses of co-formulated lopinavir/ritonavir) while on rifampin-based tuberculosis treatment had serum concentrations of lopinavir comparable to those of children treated with standard dose lopinavir/ritonavir in the absence of rifampin. Furthermore, a cohort study found similar virological and immunological outcomes of antiretroviral therapy among children treated with super-boosted lopinavir and rifampin-based tuberculosis treatment compared with children treated with standard dose lopinavir/ritonavir. Therefore, super-boosted lopinavir plus appropriate nucleoside agents is the preferred antiretroviral regimen among children on rifampin-based tuberculosis treatment.

The triple nucleoside regimen of zidovudine, lamivudine, and abacavir has been suggested for young children who are taking rifampin-based tuberculosis

treatment. However, there is limited published clinical experience with this regimen among young children, with or without concomitant tuberculosis. Furthermore, young children often have very high HIV RNA levels, suggesting the need for highly-potent antiretroviral regimens. While awaiting additional studies, the triple-nucleoside regimen is an alternative for young children receiving rifampin-based tuberculosis treatment.

In an initial pharmacokinetic study, efavirenz concentrations were not significantly different among children on rifampin, compared to children without tuberculosis. However, efavirenz concentrations were suboptimal in both groups, raising concerns about the adequacy of current efavirenz dosing recommendations among children. However, efavirenz-based antiretroviral therapy is highly-active among older children and can be used with rifampin-based tuberculosis treatment.

Patients with Multidrug-Resistant Tuberculosis

Prompt initiation of antiretroviral therapy may be one way to decrease the alarmingly high death rate among HIV-infected patients with multidrug-resistant tuberculosis.

Most of the drugs used to treat multidrug-resistant tuberculosis (the "second-line drugs": fluoroquinolone antibiotics, ethionamide, cycloserine, kanamycin, amikacin, capreomycin, para-amino salicylate) were developed and approved nearly 40 years ago, prior to the development of modern laboratory techniques to determine pathways of drug metabolism. Furthermore, there are no published studies of possible drug-drug interactions between second-line anti-tuberculosis drugs and antiretroviral drugs. Based on the existing, albeit incomplete, knowledge of the metabolism of the second-line drugs, only ethionamide has a significant possibility of an interaction with antiretroviral drugs (ethionamide is thought to be metabolized by the CYP450 system, though it is not known which of the CYP isozymes are responsible). Whether doses of ethionamide and/or certain antiretroviral drugs should be modified during the co-treatment of multidrug-resistant tuberculosis and HIV disease is completely unknown.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is not specifically stated for each recommendation.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Despite the complexities of treating two infections requiring multidrug therapy at the same time, antiretroviral therapy can be life-saving among patients with tuberculosis and advanced human immunodeficiency virus (HIV) disease. Observational studies in a variety of settings have shown that use of antiretroviral therapy during tuberculosis treatment results in marked decreases in the risk of death or other opportunistic infections among persons with tuberculosis and advanced HIV disease.

POTENTIAL HARMS

- Drug toxicities
- Drug-drug interactions

CONTRAINDICATIONS

CONTRAINDICATIONS

Efavirenz is contraindicated during at least the first 1-2 trimesters of pregnancy.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

Limitations of these Guidelines

The limitations of the information available for writing these guidelines should be appreciated. First, drug-drug interaction studies are often done among healthy volunteers. While such studies reliably predict the nature of a drug-drug interaction (e.g., that rifampin decreases the serum concentrations of efavirenz), they seldom provide the optimal management of that interaction among patients with human immunodeficiency virus (HIV)-related tuberculosis (in cases of extreme interactions, such as that between rifampin and unboosted proteaseinhibitors, the data from healthy volunteers can be definitive). In this update of the guidelines studies done among patients with HIV-related tuberculosis, particularly those that evaluate treatment outcomes of the two diseases, were emphasized. However, such studies often had small sample sizes, limiting the generalizability of their findings. Second, rates of drug metabolism often differ markedly between individuals, and part of that variance may be due to genetic polymorphisms in drug-metabolizing enzymes. Therefore, drug interactions and their relevance may not be the same in different populations. Third, in the attempt to provide the most up-to-date information the guideline developer included studies that have been presented at international conferences, but that have not yet completed the peer review process and been published. Fourth, it is very difficult to predict the outcome of complex drug interactions, such as those that might occur when three drugs with cytochrome P450 3A (CYP3A) activity are used together (e.g., rifabutin, atazanavir and efavirenz). Therapeutic drug monitoring, if available, may be helpful in such situations. Finally, in the Special Populations section, the lack of pharmacokinetic data on two key populations of patients with HIV-related tuberculosis—pregnant women and children—was highlighted. Recommendations are provided for these key populations, but these

are based primarily on expert opinion because of the lack of pharmacokinetic data.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Personal Digital Assistant (PDA) Downloads

For information about <u>availability</u>, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better Living with Illness

IOM DOMAIN

Effectiveness Safety

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Centers for Disease Control and Prevention (CDC). Managing drug interactions in the treatment of HIV-related tuberculosis. Atlanta (GA): Centers for Disease Control and Prevention (CDC); 2007 Dec. [55 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1998 Oct 30 (revised 2007 Dec)

GUIDELINE DEVELOPER(S)

Centers for Disease Control and Prevention - Federal Government Agency [U.S.]

SOURCE(S) OF FUNDING

United States Government

GUIDELINE COMMITTEE

Not stated

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version:

Centers for Disease Control and Prevention (CDC). Updated guidelines for the use of rifamycins for the treatment of tuberculosis among HIV-infected patients taking protease inhibitors or nonnucleoside reverse transcriptase inhibitors. Atlanta (GA): Centers for Disease Control and Prevention (CDC); 2004 Jan 20. 6 p. [30 references]

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or nonnucleoside reverse transcriptase inhibitor. MMWR Morb Mortal Wkly Rep 2000 Mar 10;49(9):185-9. [10 references] PubMed

GUIDELINE AVAILABILITY

Electronic copies: Available from the <u>Centers for Disease Control and Prevention</u> (CDC) Web site.

Print copies: Available from the Centers for Disease Control and Prevention, MMWR, Atlanta, GA 30333. Additional copies can be purchased from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402-9325; (202) 783-3238.

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

A variety of resources are available from the <u>Division of Tuberculosis</u>
 <u>Elimination (DTBE) home page</u> and the <u>National Center for HIV/AIDS</u>, <u>Viral Hepatitis</u>, <u>STD</u>, <u>and TB Prevention home page</u> at the Centers for Disease Control and Prevention Web site.

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on March 20, 2000. The information was updated on September 21, 2000 and April 2, 2004. This summary was updated on January 21, 2005, following the release of a public health advisory from the U.S. Food and Drug Administration regarding the use of nevirapine. This summary was updated by ECRI on June 16, 2005, following the U.S. Food and Drug Administration advisory on Sustiva (efavirenz). This summary was updated by ECRI Institute on October 2, 2007, following the U.S. Food and Drug Administration advisory on Viracept (nelfinavir mesylate). This NGC summary was updated by ECRI Institute on March 14, 2008. This summary was updated by ECRI Institute on July 28, 2008 following the U.S. Food and Drug Administration advisory on fluoroquinolone antimicrobial drugs. This summary was updated by ECRI Institute on August 11, 2008 following the U.S. Food and Drug Administration advisory on Ziagen (abacavir sulfate).

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